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09/751,780	12/30/2000	Patrick Q. Moore	2045-008	8759
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EXAMINER				
QUAN, ELIZABETH S				
		ART UNIT	PAPER NUMBER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.	09/751,780	Applicant(s)
Examiner	Elizabeth Quan	Art Unit 1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) Responsive to communication(s) filed on 26 May 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-24 is/are rejected.
- 7) Claim(s) 16 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                   | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). 9. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)        |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____   |

## **DETAILED ACTION**

### ***Claim Objections***

1. Claim 16 is objected to because of the following informalities: “corresponds to matches”. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

2. Claims 16, 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Referring to claim 16, it is unclear whether the circumferential lid flange as recited in line 2 is the same as the circumferential horizontal lid flange as recited in line 5. There is a lack of antecedent basis. Furthermore, it does not appear that the interior surface of the lid has the flange. It appears to be on the exterior surface.

4. Referring to claim 18, the planar support members do not appear to be horizontal in the drawings.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

***Claim Rejections - 35 USC § 103***

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
4. Claims 1, 2 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over U.S. Patent No. 5,092,996 to Spielberg.

Referring to claims 1, 2, Spielberg discloses a centrifuge labware device comprising a container (39) and a removable non-threaded lid (17) (see FIG. 2). The container (39) has a bottom wall and one or more substantially vertical sidewalls (see FIG. 2). The bottom wall and the one or more sidewalls cooperate to define an interior

chamber with an interior chamber cross-sectional area (see FIG. 2). The container (39) has a top opening with a first transverse axis and a second transverse axis substantially perpendicular to the first transverse axis (see FIG. 2). The top opening defines open area, which is at least about 90% of the interior chamber cross-sectional area (see FIGS. 2 and 5). The first and second transverse axes as characterized by the inner diameter of the container (39) is typically about 3.75 inches or 9.525 cm (see COL. 4, lines 66-68; COL. 5, lines 1-5). The removable non-threaded lid (17) has an exterior and interior surface (see FIG. 2). The lid (17) is sized and dimensioned to cover the top opening so as to seal the interior chamber (see FIGS. 2, 5, and 6; COL. 3, lines 3-22 and 68; COL. 4, lines 1, 2, and 26-34).

The immediate specification defines “very high axial strength” as the capability of withstanding axial forces of at least about  $1000 \times g$ , preferably at least about  $4000 \times g$ , and most preferably  $5000 \times g$  (see PAGE 7, lines 14-18). Therefore, the lid (17) has a very high axial strength since it can withstand forces up to  $5000 \times g$  for whole blood separation/fractionation (see COL. 6, lines 7-12). Since the lid (17) is designed for placement within the top of the container (39) and withstanding up to  $5000 \times g$  for whole blood separation/fractionation, it appears that the container (39) must also be able to withstand up to  $5000 \times g$  since the container (39) supporting the lid (17) also participates in centrifugation, being subjected to centrifugal forces. Furthermore, centrifugal forces affect both the exterior and interior of the container and lid. If the exterior of the lid or container can withstand  $5000 \times g$ , then the interior of the lid or container can withstand  $5000 \times g$ , and vice versa. If the container and lid has a very

high strength along its longitudinal axis such that it can withstand 5000 x gravity, then the container and lid can withstand 5000 x gravity from the inside or outside of the container. In the event one would argue that Spielberg does not explicitly disclose that the container (39) can withstand up to 5000 x gravity, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the container of Spielberg such that it can withstand up to 5000 x gravity to conform with the lid since they both participate in centrifugation and as a manufacturing expedient to make the lid and container out of the same material and since it is well known that most centrifugation processes requires forces of at least 5000 x gravity.

5. Claims 8, 10, 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,092,996 to Spielberg.

Referring to claims 8, 10, 11, Spielberg shows that the interior surface of the lid has a circumferential horizontal lid flange, circumferential vertical lid flange disposed interior to the circumferential horizontal lid flange, and vertical lid flange is spaced apart from the circumferential rim of the container (see FIG. 2). Spielberg does not disclose the circumferential horizontal lid flange with a width of at least 3 mm, vertical lid flange disposed downwardly below the horizontal lid flange by at least 3 mm, and the vertical lid flange spaced apart from the circumferential rim of the container by at least about 1 mm. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Spielberg to provide the circumferential horizontal lid flange with a width of at least 3 mm, vertical lid flange disposed downwardly below the horizontal lid flange by at least 3 mm, and the vertical

lid flange spaced apart from the circumferential rim of the container by at least about 1 mm since the Federal Circuit held that where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device (*Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), *cert denied*, 469 U.S. 830, 225 USPQ 232 (1984)). Furthermore, it has also been held that discovering the optimum or workable range involves only routine skill in the art (*In re Aller*, 105 USPQ 233).

6. Claims 1-5, 8-12, 15, 20, 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,855,289 to Moore in view of U.S. Patent No. 3,419,198 to Pettersen and U.S. Patent No. 2,849,144 to Southwell and Sargent-Welch Bottle Carrier S-9625 and U.S. Patent No. 4,874,103 to Quisenberry et al. and U.S. Patent No. 6,062,001 to Kunik.

Referring to claims 1-5, 8-12, 15, 20, 22-24, Moore discloses a centrifuge labware device (10) comprising a container (20) and a removable lid (34) (see FIG. 1). The container (20) has a bottom wall and one or more substantially vertical sidewalls (see FIG. 1). The bottom wall and the one or more sidewalls cooperate to define an interior chamber with an interior chamber cross-sectional area (see FIG. 1). The container (20) has a top opening with a first transverse axis and a second transverse axis substantially perpendicular to the first transverse axis (see FIG. 1). The top opening (30) defines open area, which is at least about 90% of the interior chamber cross-sectional area (see FIG. 1). The removable lid (34) has an exterior and interior surface (see FIG. 1). The lid (34) is

sized and dimensioned to cover the top opening (30) so as to seal the interior chamber (see FIG. 1). The lid (34) includes a curved handle (112) in the form of a hinged clip (see FIGS. 1 and 11; COL. 7, lines 41-64). The handle (112) forms a hinge or a flexible joint with the lid and clips, clasps, hooks, or grips the ribbed portion of the lid (see FIGS. 1 and 11; COL. 7, lines 41-64). The handle (112) is recessed within grooves (120) disposed in the exterior surface of the lid (34) (see FIGS. 1 and 11; COL. 7, lines 41-64). The top opening of the container (20) is defined by a circumferential rim, which matches the circumferential horizontal lid flange (see FIGS. 1, 4, 7, and 8). At least one gasket (54,98) is disposed between the circumferential rim and the circumferential horizontal lid flange (see FIG. 1; COL. 5, lines 6-8; COL. 6, lines 7-11, 20, and 21). A liner (22) is disposed within the container (20), closely fit against the walls of the container (20) (see FIG. 1). The top opening of the container (20) is defined by a circumferential rim, which matches the circumferential horizontal lid flange (see FIG. 7). The liner has one or more vertical sidewalls, which terminate in an outwardly directed circumferential horizontal line flange (see FIG. 7). The circumferential horizontal liner flange is disposed between the circumferential rim of the container and the circumferential horizontal lid flange as the circumferential liner flange is contained within the circumferential rim of the container and the circumferential horizontal lid flange (see FIG. 7). The interior surface of the bottom wall of the container (20) is bowl-shaped such that the transition of the bottom wall to the one or more sidewalls is smooth and defines no corners or edges (see FIG. 7). The centrifuge labware device (10) is disposed within a centrifuge (12) (see FIG. 2).

Moore discloses that the lid (34) of the container (20) maintains a fluid-tight seal during high-speed centrifugation, increasing the sealing force proportional to a centrifugal load to which the container is subjected (see COL. 2, lines 63-67). Since the lid withstands high-speed centrifugation, it would be of very high axial strength. Since the container participates in high-speed centrifugation with the lid, the container would be of very high axial strength as well. In the event one would argue that Moore does not explicitly disclose that the container and lid are of very high axial strength, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the container and lid to be of very high axial strength as required in performing separation of certain materials.

Moore does not explicitly disclose that the container and lid has sufficient strength to withstand 5000 x gravity applied to the interior side of the container and exterior side of the lid, respectively. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the container and lid of Moore such that it can withstand up to 5000 x gravity applied to the interior side of the container and exterior side of the lid, respectively, since it is well known that most centrifugation processes requires forces of at least 5000 x gravity.

Moore does not disclose the diameter of the opening of the container. However, it is very well known that centrifuge containers come in a variety of sizes depending on the volume of biological matter being separated. For example, centrifuge buckets for blood bags and centrifuge tubes for blood collected from a syringe. Furthermore, it has been held that where the only difference between the prior art and the claims was a recitation

of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device (*Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir 1984), *cert. denied*, 469 U.S. 830, 225 USPQ 232 (1984)). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the diameter of the container opening as necessary to hold different amounts of biological or chemical materials.

Moore discloses that the lid (34) is threaded. However, it is very well to have lids attached to the containers by means other than screwing a threaded lid to the container, such as snap-fit between a lid with a single groove and a container with a single rib, snap-fit between a lid with an inwardly projecting bead and container with an exterior bead, clamping the lid to the container, etc. Pettersen discloses a lid with an inwardly projecting bead (19) and a container with or without an exterior bead (see FIGS. 6-9; COL. 2, lines 70-72; COL. 3, lines 1-3). The lid offers secure attachment to the container with easy access into the contents of the container. Southwell discloses that lid (14) has a groove (24), which receives bead (22) of the container to lock the lid (14) to the container (see FIGS. 2, 4, and 5; COL. 2, lines 51-56). This type of fastening means permits the lid to be easily positioned on or snapped off the container (see FIGS. 2, 4, and 5; COL. 2, lines 51-56). Sargent-Welch's Bottle Carrier S-9625 discloses that a snap cover secures the contents within the carrier (see enclosed catalogue sheets). Quisenberry et al. discloses a snap-fit lid (14) that securely engages the container to prevent accidental exposure to infectious waste (see FIG. 2). Kunik discloses a non-threaded lid for

securely engaging with the container for safe disposal of sharps (see FIG. 7). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Moore to provide a non-threaded lid as in Petteron and/or Southwell and/or Sargent-Welch's Bottle Carrier S-9625 and/or Quisenberry et al. and/or Kunik as an alternative recognized equivalent of fastening means that secures the lid to the container while permitting the lid to be easily positioned on or snapped off the container.

Referring to claims 6, 7, Moore does not disclose a pouring spout, which has a sharp forward edge, in the lid with a removable self-sealing pouring spout cover. However, Petterson discloses a pouring spout, which has a sharp forward edge, in the lid with a removable self-sealing pouring spout cover (see FIG. 9). The pouring spout cover frictionally engages or seals with the pouring spout once the pouring spout cover is placed into the pouring spout when under centrifugation or not. In the instant application the pouring spout cover is also placed into the pouring spout to be self-sealed when under centrifugation. It appears that the pouring spout cover will remain frictionally engaged with the pouring spout when under centrifugation. The pouring spout and pouring spout cover provides easy access into the contents of the container and reduces contamination and chances of spilling. The sharp forward edge facilitates pouring without soiling (see FIG. 9). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Moore to provide a pouring spout with a sharp pouring edge in the lid with a removable self-sealing pouring spout

cover as in Petterson for easy access into the contents of the container, lesser contamination and chances of spilling, and facilitating pouring without soiling.

Referring to claim 9, Moore does not disclose a pouring spout with a downwardly directed portion extending downwardly below the circumferential horizontal lid flange. Quisenberry et al. disclose a pouring spout (52) extending slightly downwardly below the circumferential horizontal lid flange that assists in depositing materials into the container, reduces the chance of spillage and other contamination once materials have been deposited into the container (see FIG. 2; COL. 4, lines 4-10). Kunik discloses a pouring spout with a downwardly directed portion extending downwardly below the circumferential horizontal lid flange that guides materials into the container without accidental contact. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Moore to provide a pouring spout with a downwardly directed portion extending downwardly below the circumferential horizontal lid flange as in Quisenberry et al. or Kunik to direct materials into the container and reduce the chance of spillage and other contamination once materials have been deposited.

Referring to claims 8, 10, 11, 24, Moore shows that the interior surface of the lid has a circumferential horizontal lid flange, circumferential vertical lid flange disposed interior to the circumferential horizontal lid flange, and vertical lid flange is spaced apart from the circumferential rim of the container (see FIG. 1, 4, 7, and 8). Moore does not disclose the circumferential horizontal lid flange with a width of at least 3 mm, vertical lid flange disposed downwardly below the horizontal lid flange by at least 3 mm, and the

vertical lid flange spaced apart from the circumferential rim of the container by at least about 1 mm. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Moore to provide the circumferential horizontal lid flange with a width of at least 3 mm, vertical lid flange disposed downwardly below the horizontal lid flange by at least 3 mm, and the vertical lid flange spaced apart from the circumferential rim of the container by at least about 1 mm since the Federal Circuit held that where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device (*Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), *cert denied*, 469 U.S. 830, 225 USPQ 232 (1984)). Furthermore, it has also been held that discovering the optimum or workable range involves only routine skill in the art (*In re Aller*, 105 USPQ 233).

Referring to claim 22, Moore does not address whether the one or more sidewalls of the containers are translucent or transparent. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Moore to provide translucent or transparent sidewalls to allow viewing of the contents within the container.

7. Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,855,289 to Moore in view of U.S. Patent No. 3,419,198 to Pettersen and U.S. Patent No. 2,849,144 to Southwell and Sargent-Welch Bottle Carrier S-9625 and U.S. Patent No. 4,874,103

to Quisenberry et al. and U.S. Patent No. 6,062,001 to Kunik as applied to claim 1 above, and further in view of U.S. Patent No. 4,119,407 to Goldstein et al.

Referring to claims 17-19, Moore in view of Petterson, Southwell, Sargent-Welch Bottle Carrier S-9625, Quisenberry et al., and Kunik do not disclose a planar support member disposed within a pair of opposed first structural support slots. They also do not disclose a pair of second structural support slots spaced apart from the first structural support slots. However, Goldstein et al. disclose three pairs of opposed structural support slots and a planar support member disposed within each pair of slots to create a multi-compartmented container for holding different materials (see FIG. 2; COL. 2, lines 34-64). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Petterson and Southwell and Sargent-Welch Bottle Carrier S-9625 and Quisenberry et al. and Kunik to provide a planar support member disposed within a pair of opposed first structural support slots and at least two pairs of opposed structural support slots as in Goldstein et al. to provide a multi-compartmented container to contain different materials separately as necessary or desired.

8. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,855,289 to Moore in view of U.S. Patent No. 3,419,198 to Pettersen and U.S. Patent No. 2,849,144 to Southwell and Sargent-Welch Bottle Carrier S-9625 and U.S. Patent No. 4,874,103 to Quisenberry et al. and U.S. Patent No. 6,062,001 to Kunik as applied to claim 1 above, and further in view of U.S. Patent No. 2,191,447 to Beardsley.

Referring to claim 21, Moore in view of Petterson and Southwell and Sargent-Welch Bottle Carrier S-9625 and Quisenberry et al. and Kunik do not disclose an air vent filter in the lid. However, it is very well known to have air vent filters in the lid as disclosed in Beardsley. Particularly, Beardsley disclose an air vent filter (17) in lid (10) to keep the contents of the container free from contamination (see FIGS. 2 and 3). The filter is attached to the lid to prevent the filter from losing its effectiveness from becoming wet by contact with liquid and maintain and an airtight seal with the container (see PAGE 1; COL. 1, lines 5-39). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Moore in view of Petterson and Southwell and Sargent-Welch Bottle Carrier S-9625 and Quisenberry et al. and Kunik to provide an air vent filter in the lid as disclosed in Beardsley to keep the contents of the container free from contamination, prevent the filter from losing its effectiveness from becoming wet by contact with liquid, and maintain and an airtight seal with the container.

***Response to Arguments***

9. Applicant's arguments with respect to claims 1-24 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. They include one or more limitations in the claims.

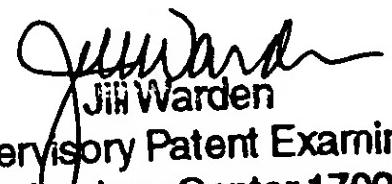
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Quan whose telephone number is (703) 305-1947. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Elizabeth Quan  
Examiner  
Art Unit 1743

eq  
August 11, 2003

  
Jill Warden  
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